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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,447	08/20/2003	Ricky W. Purcell	1443.051US1	7982
21186 7590 07/26/2007 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,447	Applicant(s) PURCELL, RICKY W.	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-43, 46, 47 and 49-62 is/are pending in the application.
- 4a) Of the above claim(s) 32-39 and 49-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 06/06/2007.

Claims 32-43, 46, 47, 49-62 are pending.

1. This application contains claims 32-39, 49-62 drawn to an invention nonelected with traverse in the reply filed on 02/07/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 44, 45 and 48 have been canceled.

Claims 40-43, 46, and 47 are included in the prosecution.

The following rejections have been overcome by virtue of applicant's amendment and remarks:

- (A) The rejection of claims 40-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.
- (B) The rejection of claims 40-48 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejections have been discussed in the previous office action in details, and are maintained for reasons of record:

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 32-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/954,764 in view of US 5,741,510 (510). The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: system and kit comprising holder, first exothermic

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patch (recited by claims 3 and 17 of the copending application), second endothermic patch (recited by claims 4 and 18 of the copending application), and third analgesic formulation.

The difference between the present claims the conflicting claims of the copending application is that the analgesic formulation instantly claimed is analgesic patch and the copending application recite the analgesic formulation as oral formulation.

US '510 teaches topical analgesic patch that has the advantage of providing excellent sustained release properties during the period of use and is more also comfortable and well tolerated by patients (abstract; col.1, lines 33-36, 47-50; col.2, lines 24-26).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide system for providing therapy to part of the body comprising holder, exothermic patch, endothermic patch, and analgesic formulation as claimed by the copending claims; and replace or select the topical analgesic patch formulation disclosed by US '510 as an analgesic formulation, motivated by the teaching of US '510 that topical analgesic patches are advantageous because they provide excellent sustained release properties during the period of use and are more comfortable and well tolerated by patients, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic patch, endothermic patch, and analgesic patch that successfully provides excellent sustained release properties during the period of use and are more comfortable and well tolerated by patients.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

4. The examiner acknowledged that applicant will consider whether filing a Terminal Disclaimer is appropriate when all claims are indicated to be otherwise allowable and if some overlap arises between the subject matter of the present application and the allowed claims of those other applications.

However, the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only remaining rejection in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other applicant into a double patenting rejection at the time the one application issues as a patent.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 40, 41, 43, 46, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,592,358 ('358).

Present claim 40 is directed to system comprising first patch, second patch and flexible wrap. Claim 41 is directed to third patch. Claim 43 requires enclosure for the patches, and claims 44-45 require container or board as a holder. Claim 46 recites more than one first patch. Claim 47 requires releasably attachment of the patches to the holder. Claim 48 recites an intended use of the flexible wrap as to secure first or second patch to the body.

US '358 disclosed therapeutic device featuring a plurality of compartments enclosing a therapeutic substance which may be a refrigerant, which reads on endothermic patch, a heat releasing substance (which reads on exothermic patch), or a high density material or weighed packets (which reads on third patch), the device may be wrapped on various body portions using strap means (abstract; col.4, lines 20-25; col.5, lines 25-26). The device comprises packets that slide easily into compartments of the device, which reads on holder as a container (col.3, lines 1-4). Packets reads on patches claimed by applicants because applicant disclosed patch as "packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure. The figures show holder that can read on board. The device comprises a plurality of compartments, but any number of compartments may actually be filled with cooling or heating packets or weights for any particular application. The reference disclosed that according to one embodiment wherein cooling or heating packets are removable, i.e. releasably attached

(col.3, lines 6-20). A single therapeutic device may be used to cool or heat, simultaneously, two different, but spaced nearby body areas (col.3, lines 26-35). The device is wrapped around the bodily injury by strap means that encircle the therapeutic device (col.5, lines 50-53). The device is flexible, and this implies that the strap is flexible so it can be wrapped around and encircles areas of the body (col.5, lines 1, 10). The limitations of claims 40, 41, 43, 46, 47 are met by US '358.

Response to Arguments

7. Applicant's arguments filed 06/06/2007 have been fully considered but they are not persuasive. Applicant traverses this rejection by arguing that '358 does not teach or suggest a container that includes at least one compartment wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container as recited in amended claim 40. Applicant further argues that the therapeutic device 10 disclosed in '358 only describes holding cooling OR heating packets and does not teach or suggest that the first and second patches which are within the therapeutic device 10 at the same time apply different types of therapy as recited in claim 40. Applicant argues that '358 does not teach or suggest a third patch held by said holder and applies a third therapy that is different than the first and second therapies, wherein the first patch, the second patch, the third patch and the flexible wrap are all within the same compartment in the container as recited in amended claim 41.

In response to this argument, applicant's attention is directed to the scope of the present claims that is directed to product and all the elements of the product are disclosed by '358. Claim 40 is directed to system comprising first patch, second patch and flexible wrap all in one container. Claim 41 is directed to third patch. Claim 43 requires enclosure for the patches. Claim 46 recites more than one first patch. Claim 47 requires releasably attachment of the patches to the container. Packets reads on patches claimed by applicants because applicant disclosed patch as "packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure.

The container does not impart patentable weight with regard to 102 rejection absent functional relationship between the container and the product, and because the product still function equally effectively with or without the container. The reference teaches three types of therapy: cooling or heating packets or weights for any particular application. Therefore, three patches are disclosed by the prior art.

Regarding applicant's argument that different therapies are applied at the same time, such limitation is directed to the intended use that imparts no patentability to claims directed to product. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In any event, the multiple packs of the prior art can be used to provide different therapies at the same time. For example, cold packs can be used in traumatically injured patient that is

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suffering from bruise, burn and bone fracture. Cold packs can be applied for these three different injuries to provide different therapies at different sites of the body at the same time.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '358 in view of US 6,245,347 ('347).

The teachings of US '358 are discussed under 102 rejection above.

Although US '358 disclosed third type of patch, however, it does not specifically teach an analgesic patch as claimed by claim 42.

US '347 teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide system for providing therapy to part of the body

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comprising holder, exothermic packet, endothermic packet, and third packet to be provided to injured portion of the body as disclosed by US '358, and replace the third packet with or further add analgesic patch that advantageously accompanied with cooling or heating means as disclosed by US '347, motivated by the teaching of US '347 that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug to relieve the pain and be involved in the treatment of the injured part of the body, with successful relief of pain or discomfort of the patient.

Response to Arguments

10. Applicant's arguments filed 06/06/2007 have been fully considered but they are not persuasive. Applicant traverses this rejection by repeating the argument regarding '358. Applicant further argues that the combination of '358 and '347 does not describe each and every element of the claimed invention, and combining '358 with '347 by altering the '358 to include a control apparatus as disclosed in '347 would destroy the stated purpose of '347 which is drug administration. Applicant argues that placing the control apparatus 100 into the compartments 12 of '358 would not allow the apparatus 100 to deliver drugs because the apparatus 100 would not engage the skin.

In response to the argument against '358, the examiner hereby repeats the argument as set forth in section 7 of this office action.

In response to the argument that the combination of '358 and '347 does not describe each and every element of the claimed invention, it is argued that in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In this case one having ordinary skill in the art at the time of the invention would have been motivated to provide system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and third packet to be provided to injured portion of the body as disclosed by US '358, and replace the third packet with or further add analgesic patch that advantageously accompanied with cooling or heating means as disclosed by US '347, motivated by the teaching of US '347 that it is advantageously to administer the

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analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug to relieve the pain and be involved in the treatment of the injured part of the body, with successful relief of pain or discomfort of the patient.

In response to applicant's argument that placing the control apparatus 100 into the compartments 12 of '358 would not allow the apparatus 100 to deliver drugs because the apparatus 100 would not engage the skin, it is argued that '347 is relied upon for the solely teaching of analgesic patch and for teaching the combination of endothermic, exothermic and analgesic patch in one device. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

isighali

ISIS GHALI
PRIMARY EXAMINER